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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,803

01/14/2005

Robert Lange

Q83451

6807

23373 7590 01/18/2008  
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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

01/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/506,803

Applicant(s)

LANGE, ROBERT

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Small et al. (US Pat. 5,129,899) in view of McMillan (US Pat. 5,556,687).

Small et al. discloses a longitudinal implant and connecting device wherein said longitudinal implant is fastenable to bones on either side of a damaged area through said connecting device, said implant and connecting device comprising: a longitudinal implant (Fig. 1, ref. 29) and a connecting device (Fig. 1, ref. 15) wherein said connecting device is operative to squeeze and lock the longitudinal implant into position both by depression caused by a squeezing and friction between the connecting device and the the longitudinal implant, and wherein the implant is one of an elongated structure (Fig. 1, ref. 29), the structure having a longitudinal slot (Fig. 1, ref. 20) extending along a substantial portion of its length (Fig. 1), and the implant is formed without any recesses adjacent to the longitudinal slot (Fig. 1). The connecting device comprising a pedicle screw (Fig. 1, ref. 15) having an upper section (Fig. 1, ref. 11) having a width greater than the width of said slot (Fig. 1, Fig. 1B) and an exteriorly threaded portion (Fig. 1, ref. 14) extending outwardly from said section and extending through said slot (Fig. 1B). An interiorly threaded nut (Fig. 1, ref. 36) is received by an outer end of said threaded

portion whereby said plate can be grasped between said upper section and said nut to tightly secure said plate by threading said upper section. The connecting device comprises a screw (Fig. 1, ref. 15) and a nut (Fig. 1, ref. 36). The implant is a rail having a rectangular cross section (Fig. 1). The implant is a plate (Fig. 1). The implant is formed with no depressions and indentations adjacent to the longitudinal slot (Fig. 1).

Small et al. disclose the claimed invention except for the longitudinal implant being made of a filament or fiber composite material, wherein filaments or fibers in said material are oriented to resist biomechanical forces, a connecting device being made of a material harder than the longitudinal implant and wherein the filaments or fibers are aligned lengthwise, so that compression will not change their strength characteristics to any extent even when compressed and wherein the implant; the longitudinal implant is made of a carbon filament composite material. The filaments are encapsulated in a polymer matrix. The filaments are encapsulated in PEEK or PEKEKK. The connecting device comprising a pedicle screw having an upper section having a width greater than the width of said slot and an exteriorly threaded portion extending outwardly from said section and extending through said slot; the screw and connecting device each are made of titanium; the filaments are woven, comprising first filaments that are oriented in axial direction of the implant, and a second filaments that are oriented perpendicular to the axial direction of the implant.

MacMillan discloses a longitudinal implant (Fig. 1, ref. 10), made of a filament or fiber composite material (column 4, lines 43-53), wherein filaments or fibers in said material are oriented (column 7, lines 65-67) to resist biomechanical forces (column 8,

lines 1-2); a connecting device (Fig. 2, ref. 20) made of a material harder than said longitudinal implant (column 3, lines 32-35) and wherein the filaments or fibers are aligned lengthwise (column 7, lines 65-67 and column 8, lines 1-2), so that compression will not change their strength characteristics to any extent even when compressed and wherein the implant; the longitudinal implant is made of a carbon filament composite material (column 4, lines 28-29). The filaments are encapsulated in a polymer matrix (column 4, lines 56-58). The filaments are encapsulated in PEEK or PEKEKK (column 4, lines 62-67); the screw and connecting device each are made of titanium (column 3, lines 32-35); and the filaments are woven (Fig. 6, ref. 102)(column 4, lines 37-42). The use of the composite material is advantageous in that it resists splitting of the bone plate (column 2, lines 4-7) and resists bending of the bone plate (column 2, lines 7-10). Furthermore, the use of composite materials in a bone plate can be helpful in preventing stress shielding (column 2, lines 21-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the longitudinal implant of Small et al. with the features as disclosed by MacMillan in order to allow the implant to resist splitting (column 2, lines 4-7) and resists bending (column 2, lines 7-10). Furthermore, the use of composite materials in a bone plate can be helpful in preventing stress shielding (column 2, lines 21-22).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Small et al. (US Pat. 5,129,899) in view of McMillan (US Pat. 5,556,687) in view of Törmälä et al. (US Pat. 5,084,051).

Small et al. in view of McMillan disclose the claimed invention except for the implant being a rod.

Törmälä et al. disclose an implant in the shape of a rod (Fig. 8)(column 11, lines 47-51) comprising a fiber reinforced composite material (column 11, lines 52-54), which can be used as fixation devices in the treatment of cancellous bone fractures, osteotomies and arthrodesis (column, 11, lines 47-51).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the longitudinal member of McMillan as a rod as taught by Törmälä et al., in order to use the implant in the treatment of cancellous bone fractures, osteotomies and arthrodesis (column, 11, lines 47-51).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Small et al. (US Pat. 5,129,899) in view of McMillan (US Pat. 5,556,687) in view of Eisermann et al. (US Pub. 2002/0123750 A1).

Small et al. in view of McMillan disclose the claimed invention except for the filaments comprising first filaments that are oriented in an axial direction of the implant, and second filaments that are oriented perpendicular to the axial direction of the implant.

Eisermann et al. disclose an implant (Fig. 4, ref. 90) comprising filaments (Fig. 4, ref. 98) that are oriented in an axial direction of an implant (Fig. 4, filaments extending from left to right) and second filaments (Fig. 4, filaments extending from top to bottom) that are oriented perpendicular to the axial direction of the implant (Fig. 4)(paragraphs 0032 and paragraph 0033), in order to allow the implant to have similar tensile properties in the x and y directions (paragraph 0032).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the implant of Small et al. in view of McMillan with the filaments comprising first filaments that are oriented in an axial direction of the implant, and second filaments that are oriented perpendicular to the axial direction of the implant as taught by Eisermann et al., in order to allow the implant to have similar tensile properties in the x and y directions (paragraph 0032).

### ***Response to Arguments***

Applicant's arguments filed 10/19/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the connecting device does not lock the plate into position by depression caused by squeezing, it is noted that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Specifically the device is capable of performing this function,

since the connecting device can be placed through the implant, which would allow the portion near ref. 178 to squeeze the implant and provide a frictional force.

With regard to Applicant's arguments regarding the motivation of combining the Small et al. reference with the McMillan reference, the examiner notes that the fibers are found in both the inner portion and the outer portion of the implant, in order to resist splitting and bending of the plate, respectively (column 2, lines 4-10). The spherical portions of ref. 44 and 48 may *help* resist splitting of the plate as stated in column 4, lines 23-27, but that does not mean that the fibers themselves do not participate in the resistance to splitting. Furthermore, the use of composite materials in a bone plate can be helpful in preventing stress shielding (column 2, lines 21-22) as stated in the previous office action.

With regard to applicant's argument that the Small et al. reference has a recessed portion since the edge is beveled, the examiner respectfully disagrees. The definition of bevel according to the Cambridge Advanced Learner's Dictionary is "a sloping edge". A slope is not recessed or depressed, but rather is slanted.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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10/506,803  
Art Unit: 3733

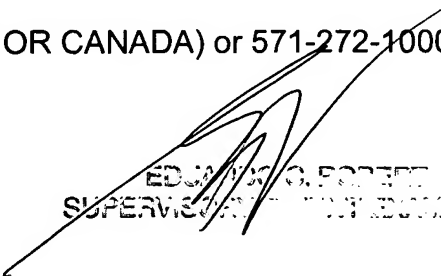
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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